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Amendment and Response

Scrial No.: 10/691,330 Confirmation No.: 1384 Filed: 22 October 2003

For: USE OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF AS

INHIBITORS OF APOPTOSIS AND OTHER CELLULAR DAMAGE

#### Remarks

The Office Action mailed 9 July 2007 has been received and reviewed. Claims 1, 12, 27, and 28 having been amended, claims 25, 26, and 29-32 having been canceled, without prejudice, and claims 33-38 having been added, the pending claims are claims 1-6, 8, 12-15, 27, 28, and 33-38. Reconsideration and withdrawal of the rejections are respectfully requested.

### **Examiner Interview**

A telephonic interview was held on 13 November 2007 between Primary Examiner Chih Min Kam and Applicant's Representative Nancy Johnson. In this interview the rejections of the claims under the judicially created doctrine of obviousness-type double patenting were discussed. Examiner Kam is thanked for the courtesy of this interview.

### Objections to the Claims

The Examiner objected to claims 25-28 and 31-32 as reciting non-elected amino acid sequences. Applicants submit that this objection is overcome in view of the cancellation of claims 25, 26, 31, and 32 and the amendment of claims 27 and 28 to recite SEQ ID NO:1-8. Claims 27 and 28 have also been amended to recite SEQ ID NO:1-8. Reconsideration and withdrawal of this objection is requested.

### The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 27 and 28 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants submit that this objection is overcome in view of the amendment of claims 27 and 28 to clarify the claimed invention. Reconsideration and withdrawal of this rejection of claims 27 and 28 under 35 U.S.C. §112, second paragraph, is requested.

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## Double Patenting Rejection over U.S. Patent No. 6,500,798

Claims 1-6, 8, and 12-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,500,798. This rejection is traversed.

Independent claim 1 and dependent claims 2-6 and 8 are drawn to a "method comprising determining an effective amount of an apoptosis inhibitor effective to inhibit apoptosis in the cell." Independent claim 12 and dependent claims 13-15 are drawn to a "method comprising... determining an effective amount of a compound effective to protect against DNA damage in the cell, wherein the compound is selected from the group consisting of colostrinin, a constituent peptide of colostrinin and combinations thereof."

Applicants submit that claims 1-8 of U.S. Patent No. 6,500,798 do not teach or make obvious methods comprising a step of "determining an effective amount of an apoptosis inhibitor effective to inhibit apoptosis in the cell" (instant claims 1-6 and 8) or a step of "determining an effective amount of a compound effective to protect against DNA damage in the cell, wherein the compound is selected from the group consisting of colostrinin, a constituent peptide of colostrinin and combinations thereof" (instant claims 12-15). Thus, instant claims 1-6, 8, and 12-15 are patentably distinct from claim 1-8 of U.S. Patent No. 6,500,798.

Reconsideration and withdrawal of the rejection of claims 1-6, 8, and 12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,500,798 is requested.

# Double Patenting Rejection over U.S. Patent No. 6,903,068

Claims 1-6, 8, and 12-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,903,068. This rejection is traversed.

Independent claim 1 and dependent claims 2-6 and 8 are drawn to a "method comprising determining an effective amount of an apoptosis inhibitor effective to inhibit apoptosis in the

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cell." Independent claim 12 and dependent claims 13-15 are drawn to a "method comprising . . . determining an effective amount of a compound effective to protect against DNA damage in the cell, wherein the compound is selected from the group consisting of colostrinin, a constituent peptide of colostrinin and combinations thereof."

Applicants submit that claims 1-10 of U.S. Patent No. 6,903,068 do not teach or make obvious methods comprising a step of "determining an effective amount of an apoptosis inhibitor effective to inhibit apoptosis in the cell" (instant claims 1-6 and 8) or a step of "determining an effective amount of a compound effective to protect against DNA damage in the cell, wherein the compound is selected from the group consisting of colostrinin, a constituent peptide of colostrinin and combinations thereof" (instant claims 12-15). Thus, instant claims 1-6, 8, and 12-15 are patentably distinct from claim 1-10 of U.S. Patent No. 6,903,068.

Reconsideration and withdrawal of the rejection of claims 1-6, 8, and 12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,903,068 is requested.

### Double Patenting Rejection over U.S. Patent No. 7,119,064

Claims 1-6, 8, and 12-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,119,064. This rejection is traversed.

Independent claim 1 and dependent claims 2-6 and 8 are drawn to a "method comprising determining an effective amount of an apoptosis inhibitor effective to inhibit apoptosis in the cell." Independent claim 12 and dependent claims 13-15 are drawn to a "method comprising . . . determining an effective amount of a compound effective to protect against DNA damage in the cell, wherein the compound is selected from the group consisting of colostrinin, a constituent peptide of colostrinin and combinations thereof."

Applicants submit that claims 1-7 of U.S. Patent No. 7,119,064 do not teach or make obvious methods comprising a step of "determining an effective amount of an apoptosis inhibitor

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effective to inhibit apoptosis in the cell" (instant claims 1-6 and 8) or a step of "determining an effective amount of a compound effective to protect against DNA damage in the cell, wherein the compound is selected from the group consisting of colostrinin, a constituent peptide of colostrinin and combinations thereof" (instant claims 12-15). Thus, instant claims 1-6, 8, and 12-15 are patentably distinct from claim 1-7 of U.S. Patent No. 7,119,064.

Reconsideration and withdrawal of the rejection of claims 1-6, 8, and 12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,119,064 is requested.

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### **Summary**

It is respectfully submitted that the pending claims 1-6, 8, 12-15, 27, 28, and 33-38 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted By Mueting, Raasch & Gebhardt, P.A. P.O. Box 581415 Minneapolis, MN 55458-1415 Phone: (612) 305-1220 Facsimile: (612) 305-1228

Decuber 10, 2007

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10 day of Cremow, 2007, at C:10 are (Central Time).

By: Dani mouse.